

B1
29. A method for the administration of a taxane to a subject in need thereof, said method comprising systemically administering said taxane to said subject in a formulation that may be safely administered using medical hardware made from materials containing extractable components.

B2
31. A method for the administration of a taxane to a subject in need thereof, said method comprising systemically administering said taxane to said subject in a formulation that may be safely administered without the use of an in-line filter.

B3
32. A method for the administration of a taxane to a subject in need thereof, said method comprising systemically administering a complete dose of said taxane to said subject in a volume of less than 250 ml.

B3
35. A method for the administration of a taxane to a human subject in need thereof, said method comprising systemically administering said taxane to said subject at a rate between 6-30 mg/m²/min over an administration period of one hour or less.

B4
46. A dry powder formulation suitable for administration of a taxane to a human subject in need thereof upon reconstitution, wherein said formulation comprises taxane nanoparticles having a mean particle size in the range of about 10 nm up to about 8 µm, wherein said formulation is substantially free of surfactant.

47. A formulation according to claim 46 wherein said formulation is lyophilized.

48. A frozen formulation of a taxane suitable for administration of a taxane to a subject in need thereof upon thawing.

49. A liquid formulation of a taxane suitable for administration to a human subject, said formulation comprising water and a taxane at a concentration of at least 2.0 mg/ml, wherein said formulation is stable for at least 3 days.

B4
canceled
50. A liquid formulation of a taxane according to claim 49, wherein said taxane concentration is at least 5.0 mg/ml.

51. A liquid formulation of a taxane according to claim 49, wherein said taxane concentration is at least 10.0 mg/ml.

52. A drug formulation suitable for administration of drug to a subject in need thereof by inhalation or oral administration, said formulation comprising at least one protein and drug nanoparticles having a size of about 10-1,000 nm, plus optionally an excipient.

66. A dry powder formulation of a taxane suitable for administration of a taxane to a subject in need thereof upon reconstitution, wherein said formulation is substantially free of surfactants.

B5
67. A dry powder formulation of a taxane suitable for administration of a taxane to a subject in need thereof upon reconstitution, wherein said formulation is substantially free of cremophor.

68. A formulation of a taxane suitable for administration of a taxane to a subject in need thereof, wherein said formulation comprises taxane nanoparticles having an average diameter in the range of about 10 nm up to about 8 μm .

69. A formulation according to claim 68, wherein said taxane nanoparticles are suitable for administration to a subject by oral, topical, ocular, intramuscular, intravenous, intraperitoneal, intraarterial, intraurethral, intrathecal, or inhalation administration.

70. A lyophilized formulation suitable for administration of a taxane to a subject upon reconstitution, wherein said formulation comprises taxane nanoparticles whose size remains substantially constant prior to and after reconstitution.

71. An article of manufacture comprising a sealed vial containing a dry powder formulation of a taxane, wherein said formulation comprises taxane nanoparticles having an average diameter in the range of about 10 nm up to about 8 μm .

Specimen
C2
72. An article of manufacture according to claim 74, wherein said formulation is stable for at least 3 days.

B5:
cont.
73. An article of manufacture comprising a dry powder or liquid formulation of drug and at least one protein, wherein said formulation comprises drug nanoparticles that have been filtered through a sterilizing filter.

74. An article of manufacture according to claim 73 wherein said drug is a taxane.

Sub C3
75. An article of manufacture according to claim 73 wherein said liquid formulation of taxane is free of surfactants

76. The method of claim 35 wherein said rate is between 6-16 mg/m²/min.

77. The method of claim 35 wherein said taxane is used to treat cancer in said human subject.

78. The method of claim 35 wherein said taxane is used to treat vascular restenosis in said human subject.

Sub C4 79. The composition of claim 46 wherein said nonoparticles have a mean particle size

in the range of about 29 nm up to about 400 nm.

80. The composition of claim 46 wherein said dry powder formulation of taxane is

suitable for the treatment of tumors in the brain or peritoneal cavity.

81. A liquid formulation of a taxane according to claim 49, wherein said taxane

concentration is at least 20 mg/ml.

B5 cont 82. A method for the administration of a taxane to a human subject in need thereof,

said method comprising systemically administering said taxane to said subject at a concentration
of at least 2 mg/ml.

83. The method of claim 82 wherein said concentration of said taxane is at least 5

mg/ml.

84. The method of claim 82 wherein said concentration of said taxane is at least 10

mg/ml.

85. The method of claim 82 wherein said concentration of said taxane is at least 20

mg/ml.

Sub C5 86. A drug formulation according to claim 52 wherein said drug nanoparticles are

contained within protein microparticles having a size of about 1-10 μm .

87. The formulation of claim 52 wherein said drug formulation may be used in

conjunction with oral bioavailability enhancers.